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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/888,362	06/22/2001	Patrick J. Muraca	5568/1012	8909

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PALMER & DODGE, LLP
PAULA CAMPBELL EVANS
111 HUNTINGTON AVENUE
BOSTON, MA 02199

EXAMINER	
FORMAN, BETTY J	
ART UNIT	**PAPER NUMBER**
1634	

DATE MAILED: 01/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/888,362	MURACA, PATRICK J.	
	Examiner	Art Unit	
	BJ Forman	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 November 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4 7-69* is/are pending in the application.

4a) Of the above claim(s) *16-34 and 66-69* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,7-15 and 35-65* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

1. This action is in response to papers filed 2 November 2004 in which claims 1, 12 and 55 were amended and a Terminal Disclaimer was filed. The amendments have been thoroughly reviewed and entered.

The previous rejections of Claims 35-65 in the Office Action dated 5 April 2004, not reiterated below, are withdrawn in view of the amendments. The previous rejections of Claims 1-4 and 7-15 are withdrawn in view of the amendments and Terminal Disclaimer. Applicant's arguments have been thoroughly reviewed but are deemed moot in view of the amendments and withdrawn rejections. New grounds for rejection are discussed.

The examiner for this application has changed. Please address future corresponded to Examiner BJ Forman, Art Unit: 1634.

Claims 1-4, 7-15, 35-65 are under prosecution.

Priority

2. Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged. However, the Provisional Applications upon which priority is claimed does not provide adequate support under 35 U.S.C. 112 for the instant claims.

The instant claims are drawn to a microarrayer comprising a cooling chamber moveable in x-y directions. Applicant points to page 8 of the '321 application for support of the instantly claimed arrayer. While the cited passage and the provisional applications teach maintaining the tissues at or below –20° C during the arraying process, they do not teach a "cooling chamber" or a chamber "moveable in x-y directions relative to fixed horizontal surface.

Hence, the provisional applications do not provide adequate support under 35 U.S.C. 112 for the instant claims. Therefore, the effective filing date for the instant claims is 22 June 2001.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 46 and 54 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 46 is indefinite for the recitation "said individual" because the recitation lacks proper antecedent basis in Claim 35.

Claim 54 is indefinite for the recitation "at least one donor" because the recitation lacks proper antecedent basis in Claim 35.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application

designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 35 is rejected under 35 U.S.C. 102(b) as being anticipated by Battifora et al (U.S. Patent No. 5,002,377, issued 26 March 1991).

Regarding Claim 35, Battifora discloses a microarray comprising a substrate (slide) on which a plurality of frozen tissue samples are disposed at a plurality of known locations (Column 3, lines 27-52 and Fig. 4). While Battifora does not teach the specific steps recited in instant Claim 1, the courts have stated that the process of making a product does not distinguish the product over the prior art product. Because Battifora teaches the product, they also teach the product as claimed.

> "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) see MPEP 2113.

7. Claims 35-40, 42-58 and 62-65 are rejected under 35 U.S.C. 102(e) as being anticipated by Li et al (U.S. Patent No. 6,406,840, filed 17 December 1999).

Regarding Claim 35, Li et al disclose a microarray comprising a substrate (slide) on which a plurality of frozen tissue samples are disposed at a plurality of known locations (Column 16, lines 50-64 and Example 2, Column 30). While Li et not teach the specific steps recited in instant Claim 1, because the courts have stated that the process of making a product

does not distinguish the product over the prior art product, Li et al disclose the product as claimed.

Regarding Claim 36, Li et al disclose the microarray wherein the sample is from a human (Column 3, lines 1-22).

Regarding Claim 37, Li et al disclose the microarray wherein the sample is from an individual having a disease human (Column 3, lines 1-22).

Regarding Claim 38, Li et al disclose the microarray wherein the disease is a progressive disease and the samples represent different stages of the disease (Column 3, line 1-22; Column 5, line 59-Column 6, line 6; and Column 11, lines 31-47).

Regarding Claim 39, Li et al disclose the microarray wherein the disease is cancer (Column 3, lines 20-21).

Regarding Claim 40, Li et al disclose the microarray wherein the disease is a neurodegenerative disease (Column 12, lines 20-25).

Regarding Claim 42, Li et al disclose the microarray wherein the samples include both tissue and cell samples e.g. blood and muscle (Column 11, lines 31-42). However, it is noted that tissue comprises cells. Therefore, the tissue array of Li comprises both tissue samples and cell samples as claimed.

Regarding Claim 43, Li et al disclose the microarray comprising a plurality of different types of tissues from the same individual i.e. a plurality of tubes, each comprising a unique cell population from a subject (Column 11, lines 31-42).

Regarding Claim 44, Li et al disclose the microarray comprising at least 5 different tissue types form the individual (Column 16, lines 17-30).

Regarding Claim 45, Li et al disclose the microarray comprising at least 10 different tissue types form the individual (Column 16, lines 17-30).

Regarding Claim 46, Li et al disclose the microarray further comprising cell samples e.g. blood (Column 11, lines 31-42). However, it is noted that tissue comprises cells. Therefore, the tissue array of Li comprises both tissue samples and cell samples as claimed.

Regarding Claim 47, Li et al disclose the microarray wherein the cell sample is from bodily fluids e.g. blood (Column 11, lines 31-42).

Regarding Claim 48, Li et al disclose the microarray wherein the at least one sample is from a fetus i.e. embryo (Column 11, lines 43-48).

Regarding Claim 49, Li et al disclose the microarray wherein at least one sample is from a non-human animal (Column 11, lines 11-20).

Regarding Claim 50, Li et al disclose the microarray wherein at least one animal comprises exogenous nucleic acid (Column 12, lines 26-44).

Regarding Claim 51, Li et al disclose the microarray wherein the non-human animal is a disease model i.e. recombinant used for screening (Column 11, lines 18-20 and Column 12, lines 26-67).

Regarding Claim 52, Li et al disclose the microarray wherein the non-human has been treated with disease-treatment e.g. drugs (Column 12, lines 26-67).

Regarding Claim 54, Li et al disclose a method of evaluating a tissue or cell sample comprising, providing a microarray of samples, contacting the microarray with a molecular probe and determining microarray locations reacting with the probe (e.g. Example 3, Column 30, lines 48-Column 31, line 2).

Regarding Claim 55, Li et al disclose the method wherein the evaluating correlating probe reactivity with an individual e.g. diagnostic (Column 23, line 60-Column 24, line 61).

Regarding Claim 56, Li et al disclose the method wherein disease is detected (Column 23, line 60-Column 24, line 61).

Regarding Claim 57, Li et al disclose the method wherein the correlating identifies a probe as a diagnostic probe (Column 23, lines 10-19).

Regarding Claim 58, Li et al disclose the method wherein at least one of the sample is from an individual treated with a drug (Column 18, lines 45-59).

Regarding Claim 62, Li et al disclose the microarray wherein the disease is cancer (Column 3, lines 20-21).

Regarding Claim 63, Li et al disclose a method of identifying probe specificity comprising, providing a microarray of samples, contacting the microarray with a molecular probe and determining which tissues react with the probe (e.g. Column 23, lines 10-19 and Example 3, Column 30, lines 48-Column 31, line 2).

Regarding Claim 64, Li et al disclose the method comprising at least 5 different tissue types form the individual (Column 16, lines 17-30).

Regarding Claim 65, Li et al disclose the method wherein the cell sample is from bodily fluids e.g. blood (Column 11, lines 31-42).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 36-65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Battifora et al (U.S. Patent No. 5,002,377, issued 26 March 1991) in view of Leighton et al (WO 99/44062, published 2 September 1999).

Regarding Claim 36-65, Battifora discloses a microarray comprising a substrate (slide) on which a plurality of frozen tissue samples are disposed at a plurality of known locations (Column 3, lines 27-52 and Fig. 4). Battifora teaches the array is useful in tissue analysis (Column 2, lines 10-23) but they are silent regarding specific tissues or analysis. However, Leighton et al teach a similar microarray encompassing a wide range of tissues and tissue analysis useful in the treatment and diagnosis of disease. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the microarray of Battifora by selecting the claimed tissue compositions for the microarray based on the well known practice of tissue analysis for disease treatment and analysis as taught by Leighton (Abstract).

10. Claims 41 and 59-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Li et al (U.S. Patent No. 6,406,840, filed 17 December 1999) in view of Leighton et al (WO 99/44062, published 2 September 1999).

Regarding Claims 41 and 59-61, Li et al disclose a microarray comprising a substrate (slide) on which a plurality of frozen tissue samples are disposed at a plurality of known locations (Column 16, lines 50-64 and Example 2, Column 30) wherein the samples are from a an individual with a neurodegenerative disease (Column 12, lines 20-25). Li et al further teach the microarray is useful for a broad range of tissues and analysis e.g. drug screening (Column 10, lines 1-49 and Column 18, lines 45-59) but they are silent regarding neuropsychiatric disease and screening drug-treated to untreated. However, their teaching of nerve tissue analysis and drug screening clearly suggests such diseases and methods. Furthermore, Leighton et al teach a similar microarray encompassing a wide range of tissues

and tissue analysis useful in the treatment and diagnosis of disease (Abstract). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the microarray of Li et for analysis of neuropsychiatric disease and screening drug-treated vs untreated as claimed based on the well known practice of tissue analysis for disease treatment and analysis as taught by Leighton (Abstract).

Conclusion

11. Claims 1-4 and 7-15 are allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741. The examiner can normally be reached on 6:00 TO 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (571) 272-0745. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will

notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

BJ Forman, Ph.D.
Primary Examiner
Art Unit: 1634
January 7, 2005